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| 10/630,660 | 07/31/2003 | Allan C. Spradling | 056100-5031 | 8247 |

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| EXAMINER |
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HUTSON, RICHARD G

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| ART UNIT | PAPER NUMBER |
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1652

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08/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/630,660

Applicant(s)

SPRADLING ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-30 and 32-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,26,28,29,33-39 and 41-48 is/are rejected.
- 7) ☒ Claim(s) 27,30,31,32,40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of claims 25, 27-29, 33, 35, 36, and the cancellation of claims 31 and 49-75, in the paper of 4/30/2007, is acknowledged. Claims 25-30 and 32-48 are still at issue and are present for examination.

Claim Objections

Claims 27, 30, 31, 32 and 40 are objected to because of the following informalities:

Claim 30 recites "of claims 28". This should be "of claim 28".

Claims 27, 30, 31 and 40 depend from rejected claims 28 and 39.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 28, 29, 38, 39, 41-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 25, 28, 29, 38-48 are directed to all possible nucleic acid molecules encoding a PARP comprising a nucleotide sequence at least 90% identical to SEQ ID NO: 10 and vectors and host cells comprising said nucleic acid. The specification, however, only provides a single representative species of SEQ ID NO: 10 encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these genomic nucleic acid sequences by any identifying structural characteristics or properties other than SEQ ID NO: 10, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 25, 26, 28, 29, 33-39, 41-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule encoding a poly (ADP-ribose) polymerase consisting of SEQ ID NO: 1, does not reasonably provide enablement for any nucleic acid molecule encoding a PARP, comprising a nucleotide sequence having a mere 90% identity to SEQ ID NO: 1 or SEQ ID NO: 10. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claims 25, 26, 28, 29, 31, 33-39 and 41-48. In response, applicants have amended claims 25, 27-29, 33, 35, 36, and cancelled claim 31 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse this rejection on the basis that applicants disclosure is more than enabling to support the claims as now presented with the at least 90% identity feature of claim 26 added to claim 25.

Applicant's complete argument is acknowledged and has been carefully considered, however continues to be found nonpersuasive on the following basis.

Applicants argument is not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., encoding a PARP) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the vast possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant

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specification. As previously stated the specification does not establish: (A) regions of the nucleic acid structure which may be modified without effecting poly(ADP-ribose) polymerase activity; (B) the general tolerance of poly(ADP-ribose) polymerase encoding nucleic acids to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a poly(ADP-ribose) polymerase with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

It is further noted that applicants have also amended the claims to include those nucleic acid molecules encoding a PARP, comprising a nucleotide sequence at least 90% identical to the genomic DNA sequence of SEQ ID NO: 10. It is noted that SEQ ID NO: 10 is a greater than 50,000 bp genomic nucleotide sequence containing many exons, introns and splice sites. Applicants have not enabled those nucleic acid molecules which are at least 90% identical to such a large nucleotide sequence.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including those nucleic acids having a mere 90% identity to SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those nucleic acids having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is

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unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchida et al. (Proc. Natl. Acad. Sci. USA, Vol 90, pages 3481-3485, May 1993).

The rejection was stated in the previous office action as it applied to previous claims 25, 28, 31, 33, 34, 35, 37, 38, 41, 42, 46 and 47. In response to this rejection applicants amended claims 25, 27-29, 33, 35, 36, and cancelled claim 31 and traversed the rejection as it applies to the newly amended claims. It is noted that applicant's amendment has resulted in claims 25, 28, 31, 41, 42, 46 and 47 being withdrawn from the rejection. It is noted that applicants only traverse this rejection as it applies to newly amended claims 25, 28, 31, 37, 38, 41, 42, 46 and 47. Applicants have not traversed the rejection as it applies to claims 33-36.

Claims 33-36 remain rejected by Uchida et al. on the basis that as previously stated, Uchida et al. specifically teach an isolated nucleic acid encoding a PARP comprising a nucleotide sequence at least 70% identical to SEQ ID NO: 1 and hybridizes to SEQ ID NO: 1. The basis of the hybridization under stringent conditions of

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the nucleic acid taught by Uchida et al. is the greater than 99% identity over the central coding region of SEQ ID NO: 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

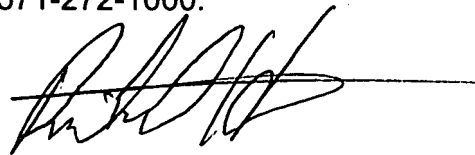
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

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7/31/2007